

## § 170.200

met all applicable certification criteria adopted by the Secretary; or

(2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

*Complete EHR* means EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary.

*Disclosure* is defined as it is in 45 CFR 160.103.

*EHR Module* means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

*Human readable format* means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

*Implementation specification* means specific requirements or instructions for implementing a standard.

*Qualified EHR* means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists; and

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality; and

(iv) To exchange electronic health information with, and integrate such information from other sources.

*Standard* means a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.

[75 FR 2042, Jan. 13, 2010, as amended at 75 FR 36203, June 24, 2010; 75 FR 44649, July 28, 2010]

## 45 CFR Subtitle A (10–1–10 Edition)

### Subpart B—Standards and Implementation Specifications for Health Information Technology

SOURCE: 75 FR 44649, July 28, 2010, unless otherwise noted.

#### § 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules.

#### § 170.202 [Reserved]

#### § 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) *Patient summary record*—(1) *Standard*. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in § 170.299). *Implementation specifications*. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in § 170.299).

(2) *Standard*. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in § 170.299).

(b) *Electronic prescribing*.—(1) *Standard*. The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in § 170.299)

(2) *Standard*. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in § 170.299).

(c) *Electronic submission of lab results to public health agencies*. *Standard*. HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299).